sequences, wherein said EPO peptide consists essentially of a peptide of less than the complete erythropoietin protein, said peptide selected from the group consisting of amino-acid positions 1 to 35 (P4), 7 to 22 (P4/1), 44 to 78 (P3), 52 to 63 (P3/1), 74 to 109 (P1), 84 to 95 (P1/1), 93 to 137 (P5), 110 to 123 (P5/1), 142 to 166 (P2) and 152 to 166 (P2/1) in accordance with the numbering of the amino-acid positions of natural EPO[, and/or directed against an EPO epitope, an epitope being defined as being composed of one or more peptides, or one or more sections of peptide sequences], comprising:

(a) immunizing an animal with said peptide; and

(b) isolating said epitope-specific EPO antibodies.

10. (Amended) [The use of the epitope-specific anti-EPO antibodies] A method of using the antibody as claimed in claim 6 for purifying EPO, an EPO [derivatives] derivative, or an EPO [peptides] peptide comprising:

(a) contacting a biological sample with said antibody, wherein said antibody is bound to a carrier material suitable for chromatography; and

(b) isolating said EPO, EPO derivative, or EPO peptide.

Please cancel claim 8 without prejudice or disclaimer of subject matter therein.

REMARKS

Applicants submit these remarks in further response to the Office Action dated March 31, 1998. Claims 5-7, 9-12 and 14-23 are under examination. Claim 8 has been

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cancelled. Claim 5 has been amended to recite positive method steps. Support for the amendment may be found in the specification, at least at pages 10 and 13-15 (particularly Examples 2 and 4). Claim 10 has been amended to recite a statutory class of invention and to recite positive method steps. Support for the amendment may be found in the specification, at least at page 6, lines 23-32. No new matter has been added by the amendments.

I. Rejection Under 35 U.S.C. § 101

Claim 10 stands rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. (Office Action at page 2.) The Examiner asserts that the "use" of epitope-specific anti-EPO antibody is not a statutory category of invention. (Id.)

Applicants have amended claim 10 to ensure that the claim is directed to a statutory class of invention. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 5, 8, 17, and 23 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. (Office Action at page 2.) The Examiner asserts that method claim 5 is vague and indefinite because it recites no positive method steps. The Examiner additionally asserts that the language "and/or directed against an EPO epitope, an epitope being defined as being composed of one or more peptides, or one or more sections of peptides" is indefinite because i) it does not follow from the first part of the sentence, and ii) it cannot be determined whether the peptides referred to are limited to the recited peptides. (Id. at sentence bridging pages 2 and 3.)

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Applicants have amended claim 5. The amended claim recites positive method steps and does not recite the rejected language. Reconsideration and withdrawal of this rejection is thefore requested.

The Examiner contends that claim 8 is vague and indefinite because it is unclear how it further limits claim 6. (Office Action at page 3.) Applicants have cancelled claim 8, thus rendering this rejection moot.

The Examiner asserts that claims 17 and 23 should recite that the anti-erythropoietin antibody is directed against epitopes on EPO that bind to the EPO receptor. (Id.)

Applicants respectfully submit that the Examiner has offered insufficient basis for requiring addition of this limitation. The specification teaches that the anti-EPO antibodies of the present invention may be directed against epitopes on, inter alia, EPO, EPO peptides, and EPO derivatives. (See, e.g., page 1, paragraph 1.) One skilled in the art would understand what is being claimed when the claims are read in light of the specification. Thus, the claims are not indefinite. Applicants therefore request reconsideration and withdrawal of this rejection.

III. Obviousness-Type Double Patenting

Claims 7 and 19 stand rejected for obviousness-type double patenting over claims 1 and 2 of U.S. Patent No. 5,712,370. (Office Action at page 3.)

Applicants request that the rejection be held in abeyance until allowable subject matter has been indicated.

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IV. Rejection Under 35 U.S.C. § 102

Claims 5, 6, 8, 10-12, 17, 18, 20, 22, and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lin et al. (hereinafter "Lin"). (Office Action at page 5.)

The Examiner asserts that Lin discloses, at column 36, lines 31-34, polyclonal antibodies raised against a peptide representing amino acids 144-166 of EPO, which represents a section of claimed EPO peptides P2 and P2/1, and that the antibodies were shown to specifically bind EPO. (Id.)

The Examiner acknowledges that Lin is silent on the issue of the ability of the prior art antibodies to neutralize the biological activity of EPO, but argues that i) the peptide disclosed by the reference falls within P2; ii) the specification indicates that the claimed neutralizing antibodies are directed against peptides 138-166 (P2) and 152-166 (P2/1); and iii) since antibodies raised against both P2 and P2/1 have neutralizing ability, one of ordinary skill in the art would conclude that antibodies with neutralizing ability bind an epitope somewhere within amino acids 152-166 of EPO. (Id.) The Examiner asserts that, in the absence of evidence to the contrary, one would conclude that Lin's polyclonal antibodies, which are directed to a peptide containing the same epitope recognized by the instant antibodies, inherently possess the ability to neutralize the biological activity of EPO (Id.) Finally, the Examiner asserts that Lin discloses isolation and detection of EPO using their antibodies.

Applicants traverse this rejection and respectfully submit that the rejection is improper because the Examiner has failed to show that Lin teaches each and every element of the recited claims. The Examiner apparently based the rejection on, inter

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alia, Lin's disclosure of an EPO peptide containing amino acids 144-166. Although there may be similarities between the amino acid sequences of the Lin peptide and the claimed peptide, mere similarities are insufficient to render the recited claims anticipated. For anticipation, the law requires identity between the claimed invention and the prior art disclosure. Lin does not disclose the claimed peptides, antibodies or methods of using the same. Moreover, Lin does not disclose the claimed diagnostic aids for neutralizing antibodies or EPO receptors.

For these reasons, Applicants request reconsideration and withdrawal of this rejection.

V. Rejection under 35 U.S.C. § 103

Claims 9, 14-16, and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin. (Office Action at page 7).

While acknowledging that Lin does not disclose anti-idiotypic antibodies or antibody preparations in pharmaceutically acceptable form, the Examiner asserts that anti-idiotypic antibodies are conventionally used to characterize the antibodies they are raised against, and that it would therefore have been obvious for one of ordinary skill in the art to have used Lin's antibodies to make anti-idiotypic antibodies to further characterize the first antibodies. (Id.) The Examiner further asserts that it is conventional to store antibodies used in diagnostic applications in physiological buffers, and that it would also have been obvious for one of ordinary skill in the art to store Lin's antibodies in a pharmacologically acceptable form. (Id.)

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Applicants traverse this rejection and, for the following reasons, respectfully submit that the Examiner has failed to establish a prima facie case of obviousness.

First, the Examiner has offered no evidence showing that Lin would have provided either a motivation to make the claimed invention or a reasonable expectation of success of making the claimed invention had the skilled artisan chosen to do so. Thus, the Examiner failed to satisfy his burden.

Second, it appears that the Examiner has applied an obvious to try standard, and it is well-settled law that this is not the proper standard for assessing obviousness. In re Fine, 5 USPQ2d 1596,1599 (Fed. Cir. 1988).

Third, as the Examiner has acknowledged, Lin neither teaches nor suggests anti-idiotypic antibodies. Merely asserting the general motivation to make anti-idiotypic antibodies does not establish the existence of a motivation to make the claimed anti-idiotypic antibodies, as is required by law.

Fourth, the obviousness of using "Lin's antibodies" to make anti-idiotypic antibodies is irrelevant to the obviousness of making the claimed antibodies. Moreover, the Examiner has failed to show that using "Lin's antibodies" would not have resulted in the claimed anti-idiotypic antibodies.

Finally, the obviousness of storing "Lin's antibodies" in a pharmacologically acceptable form is irrelevant to the issue of whether the claimed antibodies, pharmaceutical compositions and diagnostic aids would have been obvious to those of skill in the art.

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For these reasons, Applicants request reconsideration and withdrawal of this rejection.

To the extent any extension of time under 37 C.F.R. 1.136 is required to obtain entry of this response, such extension is hereby requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed, including any fees required for an extension of time under 37 C.F.R. 1.136, please charge those fees to our Deposit Account No. 06-916.

Respectfully submitted,

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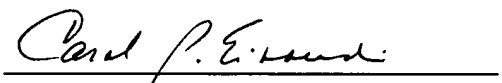
By: 
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